Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1037562	11/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Westlake Dermatology And Cosmetic Surgery	8825 Bee Caves Road 2nd Floor, Austin, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, found that the laboratory director failed to ensure that one of six testing personnel held the appropriate education for performing high complexity testing, and one of six testing personnel had documented training for performing gross analysis of tissue specimens (See to D 6102)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on review of the CMS 209 Laboratory Personnel Report, laboratory personnel records, patient test records and staff interview, the laboratory director failed to ensure one of six testing persons had documentation of appropriate education for performing gross analysis of tissue specimens, and two of six testing personnel had documentation of training prior to performing gross analysis of tissue Specimens. (see D6171)
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: The laboratory director failed to ensure there was a procedure in place to assess the competency all testing personnel involved in preanalytic, analytic and postanalytic testing of histopathology specimens. (See D6121)
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Review of the CMS 209 Laboratory personnel Report, personnel records and interview of facility personnel found that the Technical Supervisor failed to evaluate the competency of all supervisors, consultants and testing personnel performing high complexity procedures in histopathology. Findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found that the laboratory designated one general supervisor, three technical supervisors, and six testing personnel for high complexity testing. 2. Review of personnel files found no documentation of competency assessment for 2017, 2018 and 2019 for the general supervisor, technical supervisors, and three of six testing personnel. Testing persons 1,2 and 6 had no documentation of competency assessment between 2017 and 2019. Peer reviews used to assess the accuracy of results at least twice each year were offered as documentation of competency assessments for testing persons 1, 2 and 6. 3. Interview of technical supervisor two conducted on November 14, 2019 at 3:14 PM confirmed that the laboratory had not evaluated the competency of the doctors performing high complexity procedures.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.

	1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records, patient test records and staff interview, found that the laboratory failed to ensure that one of six testing personnel held the appropriate education for performing gross analysis of tissue specimens and one of six testing personnel had documented training for performing gross analysis of tissue specimens. (See to D 6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the

	factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS 209 Laboratory Personnel Report, laboratory personnel records, patient test records and staff interview, the laboratory failed to ensure one of six testing persons had documentation of appropriate education for performing gross analysis of tissue specimens, and one of six testing personnel had documentation of training prior to performing gross analysis of tissue Specimens The findings included: 1. The laboratory listed six testing personnel on the CMS-209 Laboratory Personnel Report. 2. Review of personnel files found : a. Testing Person four (hired May 2017) held an Associate of Science degree in Physics. Review of transcripts found she had not received 24 semester hours of medical laboratory technology courses; or 24 semester hours of science courses that include: Six semester hours of chemistry; Six semester hours of biology; and Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and Have laboratory training that includes either of the following: Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS, or at least 3 months documented laboratory training in gross analysis of tissues. b. Testing person five (hired September 2019) had no documentation of training for performing gross analysis of tissue specimens. 3. Review of patient test records found testing person four had performed gross analysis of tissue specimens for 127 patient specimens between May 2017 and November 14, 2019, and Testing person 5 had performed 137 gross analysis of tissue specimens between September 2019 and November 14, 2019. 4. Interview of testing person 4 on the CMS report 209 conducted November 14, 2019 at 2:53 PM confirmed these findings.